IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

 $\hat{\mathbf{R}}$ re the Application of:

Group Art Unit: 1646

Jun Feng et al.

Examiner: Not Yet Assigned

Serial No.: 10/809,635

Filed: March 24, 2004

For: DIPEPTIDYL PEPTIDASE

INHIBITORS

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO-1449, and copies are included for the Examiner's convenience. As the Office no longer requires copies of U.S. patents and applications, the U.S. copies are not being submitted with this IDS. However, if the Examiner would like copies of the U.S. cited references, Applicants will provide the references upon request. The item listed on the attached form PTO-1449 at "EN" is a non-English language article. In accordance with 37 CFR § 1.98(a)(3)(i), the following is a concise explanation of the relevance of this article:

The article by P.O. Bezuglyi relates to the synthesis of arylsulfonyl hydrazides of 3-R-quinazolone-4-carbonyl-2-acid.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicants as such.

INFORMATION DISCLOSURE STATEMENT FILING PROVISION:

\boxtimes	This I	OS is believed to be timely in that it is being submitted under 37 CFR §
1.97(b), that i	is (1) within three months of the filing date of the application, which is not a
continu	ued pro	osecution application filed under § 1.53(d); or (2) within three months of
entry o	of the n	ational stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a
first Of	fice ac	tion on the merits; or (4) before the mailing of a first Office action after filing
a requ	est for	continued examination under § 1.114. Thus, no fee is required.
	\boxtimes	However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR §1.17(p) to the deposit account referenced below.
		However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.
Office	action	OS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice under 37 CFR § 1.311.
		The fee due under 37 CFR § 1.17(p) is submitted herewith.
		A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.
payme	37 CFI ent of th	OS is being submitted under 37 CFR § 1.97(d), that is after a Final Action R § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before he issue fee. A statement under 37 CFR § 1.97(e) is included below. The er 37 CFR § 1.17(p) is submitted herewith.
		STATEMENT UNDER 37 CFR § 1.97(e):
	Each i	tem contained in this IDS was first cited in any communication from a
foreigr	paten	t office in a counterpart foreign application not more than three months
prior to	the fil	ing of this IDS.
	No ite	m contained in this IDS was cited in a communication from a foreign patent
office i	n a co	unterpart foreign application, and, to the knowledge of the person signing

this statement after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

	Payment and/or Authorization to Charge Fees:
	A check in the amount of is enclosed for the above fee(s).
	Please charge to Deposit Account No. 50-2256 for the above fee(s).
	Although Applicants do not believe any fees are required, the Commissioner is rized to charge any fees required by the filing of these papers to Syrrx's Deposit unt No. 50-2256.
	Respectfully submitted,
	SYRRX, INC.
Dated	By: David J. Weitz Beg. No. 38 362

Customer No. **32793**Syrrx, Inc.
10410 Science Center Drive
San Diego, CA 92121
Tel: (858) 622-8528

Approved for use through 07/31/2006. OMB 0651-0030 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitu	ite for form 1449	A/PTO		Complete if Known				
				Application Number	10/809,635			
INFO	ORMATI	on dis	CLOSURE	Filing Date	March 24, 2004			
STA	TEMEN	T BY A	PPLICANT	First Named Inventor	Jun Feng			
	•			Group Art Unit	1646			
	(use as mai	ny sheets as	necessary)	Examiner Name	Not Yet Assigned			
Sheet	1	of	10	Attorney Docket Number	SYR-DPP-IV-5004-U	77		

			U.S. PATENT	DOCUMENTS	\ <u>ž</u>	
Examiner Initials *	Cite No.1	Document Number Number - Kind Code ² (if known)	Publication Date/ Issue Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Releva	
		`	MM-DD-YYYY		Figures Appear	
	AA	US1974/3823135	07-09-1974	Pilgram et al.		
	AB	US1996/5512549	04-30-1996	Chen et al.		
	AC	US1996/5580979	12-03-1996	Bachovchin		
	AD	US1997/5614492	03-25-1997	Habener		
	AE	US2000/6156739	12-5-2000	Griffin et al.		
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	AH	US2001/0020006-A1	09-06-2001	Demuth et al.		
	Al	US2001/6303661-B1	10-16-2001	Demuth et al.		
	AJ	US2001/6319893-B1	11-20-2001	Demuth et al.		
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	ВВ	US2003/0153509-A1	08-14-2003	Bachovchin et al.		
	ВС	US2003/0162820-A1	08-28-2003	Demuth et al.		
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	BE	US2003/6620910-B1	09-16-2003	Calas et al.		
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<u> </u>	BG	US2003/0199451-A1	10-23-2003	Mogensen et al.		
	ВН	US2003/0199672-A1	10-23-2003	Knudsen et al.		

Date Considered	
	Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute	for form 1449A/PTC)			Complete if Known
3				Application Number	10/809,635
INFO	RMATION	DIS	CLOSURE	Filing Date	March 24, 2004
STAT	TEMENT B	Y A	PPLICANT	First Named Inventor	Jun Feng
				Group Art Unit	1646
(use as many sheets as necessary)			necessary)	Examiner Name	Not Yet Assigned
Sheet	2	of	10	Attorney Docket Number	SYR-DPP-IV-5004-U

BI	US2003/0236272-A1	12-25-2003	Richard David Carr	
BJ	US2004/6703238-B2	03-09-2004	Bachovchin	
BK	US2004/0054171-A1	03-18-2004	Jensen et al.	
BL	US2004/0058876-A1	03-25-2004	Hoffmann et al.	
ВМ	US2004/0132732-A1	07-08-2004	Han et al.	
 BN	US2004/0167191-A1	08-26-2004	Demuth et al.	
 ВО	US2004/0171555-A1	09-02-2004	Demuth et al.	

	FOREIGN PATENT DOCUMENTS							
Examiner	Cite	Foreign Patent Document	Publication		Pages, Columns, Lines, Where			
Initials*	No.1	Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	T ⁶		
	BP	FR 2.162.106 (English Abstract-1973)	11-30-1972	Amschler et al.				
	BQ	WO 89/10701 ,	11-16-1989	BASF				
	BR	EP 0378255-A2	07-18-1990	Janssen Pharmaceutica				
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	BV	WO 93/08259 (A2)	04-29-1993	New England Medical Center Hospitals, Inc.				
	BW	WO 93/08259 (A3)	04-29-1993	New England Medical Center Hospitals, Inc.				
	ВХ	EP 0547442-A1	06-23-1993	E.R. Squibb & Sons, Inc.				
	BY	WO 94/03055	02-17-1994	U.S. Government, Secty. HHS				
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	CA	WO 95/35031	12-28-1995	La Trobe University				
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	CC	WO 96/38550	12-05-1996	Dana-Farber Cancer Institute, Inc.				
	CD	WO 97/40832	11-06-1997	Hans-Knoll-Institut Fur Naturstoff				
	CE	JP 9295977 .	11-18-1997	Terumo Corp.				
	CF	WO 98/00439	01-08-1998	Trustees of Tufts College				
	CG	WO 98/24780 ·	06-11-1998	Amgen Inc.				
	CH	WO 99/16864	04-08-1999	Point Therapeutics, Inc.				
	CI	WO 99/38501 -	08-05-1999	Trustees of Tufts University				

Examiner	Date	
Signature	Considered	

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				Application Number	10/809,635	
INFO	PRMATI	on dis	CLOSURE	Filing Date	March 24, 2004	
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				Group Art Unit	1646	
(use as many sheets as necessary)			necessary)	Examiner Name	Not Yet Assigned	
Sheet	3	of	10	Attorney Docket Number	SYR-DPP-IV-5004-U	

С	WO 99/50249	10-07-1999	Du Pont Pharmaceuticals Company		
CI	WO 99-61431 .	12-02-1999	Probiodrug		
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CI	WO 00/07617	02-17-2000	Novo Nordisk	· · · · ·	
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D	WO 03/002593-A2	01-09-2003	Probiodrug AG		
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D	WO 03/030946-A1	04-17-2003	Novartis AG		
DI	MO 03/033524-A2 .	04-24-2003	Probiodrug AG		
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Di	WO 03/045228-A2	06-05-2003	Trustees of Tufts College		
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D:	WO 03/048158-A1	06-12-2003	Bristol-Myers Squibb Company		
D	WO 03/057200-A2	07-17-2003	Novo Nordisk		

Examiner Signature	Date Considered	
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	Complete if Known	
Application Number	10/809,635	
Filing Date	March 24, 2004 Jun Feng	
First Named Inventor		
Group Art Unit	1646	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	SYR-DPP-IV-5004-U	
08-07-2003	Probiodrug AG	
09-04-2003	Probiodrug AG	
10-09-2003	Probiodrug AG	
	Filing Date First Named Inventor Group Art Unit Examiner Name Attorney Docket Number 08-07-2003 09-04-2003	

J DU J	WO 03/063903-A2	08-07-2003	Probiodrug AG	i i
DV	WO 03/072556-A1	09-04-2003	Probiodrug AG	
DW	WO 03/082898-A2 .	10-09-2003	Probiodrug AG	
DX	WO 03/092605-A2	11-13-2003	Trustees of Tufts College	
DY	WO 03/099279-A1 _	12-04-2003	Novartis AG	
DZ	WO 03/099818-A1	12-04-2003	Chiron Corporation	
EA	WO 03/106416-A2 ·	12-24-2003	Smithkline Beecham Corporation	
 EB	WO 2004/017989-A1	03-04-2004	Probiodrug AG	
EC	JP 2004/99600-A ·	04-02-2004	Sankyo Co. Ltd.	
ED	WO 2004/031374-A2	04-15-2004	Probiodrug AG	
EE	JP 2004/123738-A ·	04-22-2004	Takeda Chem Ind Ltd	
EF	WO 2004/037176-A2	05-06-2004	Bristol-Myers Squibb Company	

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	EG	ARGAUD, DORIANE et al., Metaformin decreases gluconeogenesis by enhancing the pyruvate kinase flux in isolated rat hepatocytes, European J. Biochem. 213, 1341-1348 (1993).	
	EH .	ASHCROFT, STEPHEN J.H. et al., Structure-activity relationships of alloxan-like compounds derived from uric acid, Br. J. Pharmac. (1986), 89 pp. 469-472.	
	EI	BAL, GUNTHER, Dipeptidyl Peptidase IV and Prolyl Oligopeptidase: Design, Synthesis and Evaluation of Substrates and Inhibitors, (2002) Universiteit Antwerpen.	
	EJ .,	BARAKAT, S.E.S., Synthesis and hypoglycemic activity of some new 3-[4- [[[(cyclohexylamino) carbonyl] amino]sulfony]phenyl]-4(3H)-quinazolinones, Az. J. Pharm. Sci., Vol. 25, (2000), pp. 48-57.	
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	EL -	BAKER, B.R. et al., Irreversible Enzyme Inhibitors. On the Mode of Pyrimidine Binding of 5-alkyl and 5-Arylpyrimidines to Dihydrofolic Reductase (1,2), Journal of Heterocyclic Chemistry Vol. 4 (1967) pp. 39-48.	
	ЕМ	BELGODERE, ELENA et al., Synthesis of Substituted Pyrimidines, Study of the Structure and of the Tautomeric Equilibria, (1976) Chem. Abstracts, Columbus, OH Vol. 85 No. 9.	
	EN -	BEZUGLYI, P.O. et al., Synthesis of arylsulfonyl hydrazide of 3-R-quinazolone-4-carbonyl-2-acid, Pharmaceutical Journal (1979), pp. 70-71.	

Examiner	Date	
Signature	Considered	

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Substitute	for form 1449A/PTO				Complete if Known
				Application Number	10/809,635
INFO	RMATION	DIS	CLOSURE	Filing Date	March 24, 2004
STAT	TEMENT BY	YA	PPLICANT	First Named Inventor	Jun Feng
				Group Art Unit	1646
	(use as many she	ets as	necessary)	Examiner Name	Not Yet Assigned
Sheet	5	of	10	Attorney Docket Number	SYR-DPP-IV-5004-U

	EO	BHADURI, A.P. et al., Urinary Metabolite of 2-Piperazino-3 (H)-4-Quinazolone (Centpiperalone), A Potent Blood Sugar Lowering Agent, Indian J. Biochem. Biophys., Vol. 12 (1975), pp. 413-414.
	EP ,	BOURAS, MOHAMMED, et al., Metabolism of enterostatin in rat intestine, brain, membranes and serum: differential involvement of proline-specific peptidases, Peptides, Vol. 16, No. 3, (1995), pp. 399-405.
	EQ	BRUN, JEAN-FREDERIC, et al., Effects of Oral Zinc Gluconate on Glucose Effectiveness and Insulin Sensitivity in Humans, Biological Trace Element Research Vol. 47 (1995), pp. 385-391.
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	EU	COPPOLA, GARY M. et al., 1-Aminomethylisoquinoline-4-carboxylates as Novel Dipeptidylpeptidase IV Inhibitors, Bioorganic & Medicinal Chemistry Letters Vol. 10 (2000), pp. 1555-1558.
	EV ·	DEACON, CAROLYN F. et al., Degradation of Glucagon-Like Peptide 1 in Vitro Yields an N-Terminally Truncated Peptide That is a Major Endogenous Metabolite in Vivo, Journal of Clinical Endocrinology and Metabolism Vol. 80, No. 3 (1995), pp. 952-957.
·	EW	DEACON, CAROLYN F. et al., Both Subcutaneously and Intravenously Administered Glucagon-Like Peptide I Are Rapidly Degraded From the NH ₂ -Terminus in Type II Diabetic Patients and in Healthy Subjects, Diabetes, Vol. 44 (1996), pp. 1125-1131.
	EX .	DEACON, CAROLYN F. et al., Dipeptidyl peptidase IV Inhibition Influences GLP-1 Metabolism in Vivo, Regulatory Peptides Vol. 64 Issues 1-3 (1996) p.30.
	EY	DEACON, CAROLYN F. et al., Dipeptidyl peptidase IV Inhibition Potentiates the Insulinotropic Effect of Glucagon- Like Peptide 1 in the Anesthetized Pig, Diabetes, Vol. 47 (1998), pp. 764-769.
	EZ .	DEACON, CAROLYN F. et al., Dipeptidyl peptidase IV Inhibition as an Approach to the Treatment and Prevention of Type 2 Diabetes: a Historical Perspective, Biochemical and Biophysical Research Communications 294 (2002), pp. 1-4.
	FA	DEMUTH, HANS-ULRICH et al., Rebuttal to Deacon and Holst: "Metaformin effects on depeptidyl peptidase IV degradation of glucagons-like peptide-1" versus "dipeptidyl peptidase inhibition as an approach to the treatment and prevention of type 2 diabetes: a historical perspective" Biochemical and Biophysical Research Communications 296 (2002) pp. 229-232.
	FB .	ENGEL, MICHAEL et al., The crystal structure of dipeptidyl peptidase IV (CD26) reveals its functional regulation and enzymatic mechanism, Proc. Nat. Acad. Sci. Early Edition (2003), pp. 1-6.
	FC	FANTUS, I. GEORGE, et al., Mechanism of Action of Metformin: Insulin Receptor and Postreceptor Effects in Vitro and in Vivo, J. Clinical Endocrinology & Metabolism (1986), pp. 898-905.

Examiner	Date	
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INFO	DRMATION	DIS	CLOSURE	Filing Date	March 24, 2004
STA	TEMENT BY	Y A	PPLICANT	First Named Inventor	Jun Feng
				Group Art Unit	1646
	(use as many she	ets as	necessary)	Examiner Name	Not Yet Assigned
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